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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

"DOCUMENT ELECTRONICALLY FILED"

DIK DRUG COMPANY and KING DRUG COMPANY OF FLORENCE, INC. On behalf of themselves and all others similarly situated,	:Civil Action No.:
Plaintiffs,	
V.	
ALTANA PHARMA AG, ALTANA INC., ALTANA PHARMA US, INC., WYETH and WYETH PHARMACEUTICALS INC.	**CLASS ACTION COMPLAINT JURY TRIAL DEMANDED**
Defendants.	

Plaintiffs, doing business at the addresses set forth in paragraphs 13 and 14 hereof, on behalf of themselves and all others similarly situated, for their Class Action Complaint ("Complaint") against Defendants, allege as follows based on: (a) personal knowledge; (b) the investigation of their counsel, and (c) information and belief:

NATURE OF THE ACTION

1. This civil antitrust action arises out of Defendants' unlawful scheme to illegally maintain their monopoly in the United States market for their brand name prescription drug Protonix and its AB-rated generic equivalents. The generic name for Protonix is pantoprazole sodium.

2. As alleged in greater detail herein, Defendants engaged in a scheme that involved the commission of fraud before the United States Patent and Trademark Office ("PTO") in order to obtain U.S. Patent No. 4,758,579, issued July 19, 1988, (the "'579 Patent"), which, in the absence of fraud, would not have issued. Defendants then proceeded to list the fraudulently obtained '579 Patent in the Food and Drug Administration's ("FDA") Orange Book in order to be able to block the market entry of any potential generic competitor who sought FDA approval for a competing generic version of Protonix. Defendants also proceeded to institute infringement litigation against potential generic competitors knowing that: the '579 Patent was obtained by fraud; a claim of patent infringement could not reasonably be asserted against generic manufacturers because the '579 Patent was unenforceable or otherwise invalid because it was obvious in view of the prior art; and filing of such litigation would automatically prohibit the FDA from granting approval to any of the generic manufacturers for up to 30 months.

3. Defendants illegally and intentionally manipulated the patent listing and litigation provisions of the 1984 amendments to the Food, Drug, and Cosmetic Act added by the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act or Amendments. *See* Pub.L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271(e)). As many courts have recognized, these

amendments were principally designed to streamline the process by which generic drugs are brought to market.

4. Defendants knew that under the Hatch-Waxman Amendments the mere filing of the patent litigation would bar the FDA from granting marketing approval to any of the competing generic companies for up to 30 months, even though the '579 Patent was fraudulently obtained. Thus, Defendants were able to block generic competition for years simply by listing the fraudulently obtained '579 Patent in the Orange Book, and reflexively filing suit against would be generic competitors.

5. Absent Defendants' unlawful conduct, generic Protonix would have been on the market by no later than April 19, 2006. Through its unlawful conduct, Defendants illegally deprived Plaintiffs (and the other direct purchasers who comprise the Class alleged herein) of access to lower-priced generic versions of Protonix, thereby causing Plaintiffs and the Class (as defined below) to overpay for Protonix by hundreds of millions of dollars.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this civil action pursuant to 28 U.S.C. §§ 1331 and 1337.

7. Venue is proper in this Court under 28 U.S.C. § 1391 and 15 U.S.C. § 22 because each Defendant is an inhabitant of this District or is found or transacts business here.

TRADE AND COMMERCE

8. Defendants received FDA approval for a 40mg delayed-release tablet version of Protonix on February 2, 2000, and launched the product in May 2000.

9. Defendants subsequently received FDA approval for a 20mg delayed-release tablet version of Protonix on June 12, 2001, and launched the product shortly thereafter.

10. At all material times, Protonix was shipped across state lines and sold by Defendants to customers located outside the state of manufacture.

11. During the relevant time period, in connection with the purchase and sale of Protonix, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

12. During the relevant time period, various devices were used to effectuate the conspiracy alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce and the internet. The activities of Defendants as charged in this complaint were within the flow of, and have substantially affected, interstate commerce.

PARTIES

13. Plaintiff Dik Drug Company ("Dik") is a corporation organized under the laws of the State of Illinois and is located at 160 Tower Drive, Burr Ridge, Illinois, 60527. Dik purchased Protonix directly from Defendants during the Class Period, as defined below.

14. Plaintiff King Drug Company of Florence, Inc. ("King") is a corporation organized under the laws of the State of South Carolina and is physically located at 605 W. Lucas Street, Florence, South Carolina, 29501, with a mailing address at 3333 Wrightsville Avenue, Suite N, Wilmington, North Carolina, 28403. King purchased Protonix directly from Defendants during the Class Period, as defined below.

15. The Plaintiffs referred to in paragraphs 13-14 above are collectively referred to as "Plaintiffs."

16. Defendant Altana Pharma AG ("Altana") is a corporation incorporated and existing under the laws of Germany, having its principal place of business at Byk-Gulden-Str. 2, 78467 Konstanz, Germany. Altana has two United States subsidiaries:

(a) Altana Inc., having its principal place of business at 60 Baylis Road, Melville, New York, 11747; and

(b) Altana Pharma US, Inc., having its principal place of business at 210 Park Avenue, Florham Park, New Jersey, 07932.

17. Altana is the owner of United States Patent No. 4,758,579, which was issued on July 19, 1988.

18. Defendant Wyeth is a Delaware corporation with its headquarters located at Five Giralda Farms, Madison, New Jersey, 07940. Wyeth is the exclusive licensee of the '579 Patent in the United States.

19. Defendant Wyeth's wholly-owned subsidiary, Wyeth Pharmaceuticals Inc., is the holder of New Drug Application ("NDA") No. 20-987, by which the FDA first granted approval for Protonix.

20. Under the terms of a licensing agreement between Wyeth and Altana, Altana granted Wyeth an exclusive license to carry our certain manufacturing tasks with respect to semi-finished pantoprazole-based products supplied by Altana and to distribute the resulting drugs in the U.S. market.

21. The Defendants identified in paragraphs 16-19 above, are collectively referred to as "Defendants." Throughout the Class Period, as defined below, Defendants manufactured,

marketed, distributed and sold substantial quantities of Protonix in a continuous flow of interstate trade and commerce, and Defendants' activities complained of herein were within the flow of and substantially affected interstate trade and commerce.

CLASS ALLEGATIONS

22. Plaintiffs bring this action on behalf of themselves and the following class (the "Class"):

> **All persons and entities in the United States who purchased Protonix directly from Defendants from April 19, 2006 through the present. Excluded from the class are Defendants, its parents, employees, subsidiaries and affiliates, and all federal government entities.**

23. The Class is so numerous that joinder of all members is impracticable. Plaintiffs believe that the class numbers in the dozens.

24. There are questions of law or fact common to the Class, including:

a. whether Defendants had monopoly power in the relevant market;

b. whether the '579 Patent was obtained as a result of fraud committed by Defendants upon the PTO;

c. whether Defendants improperly submitted the '579 Patent to the FDA for listing in the Orange Book;

d. whether the patent infringements suits Defendants initiated against generic competitors Teva and Sun constituted sham litigation;

e. whether Defendants' actions illegally maintained its monopoly power in the relevant market;

f. whether Defendants' activities as alleged herein have substantially affected interstate commerce; and

g. whether, and to what extent, Defendants' conduct caused antitrust injury to the business or property of its direct purchaser customers and if so, the appropriate measure of damages.

25. These and other questions of law and fact are common to the members of the Class and predominate over any questions affecting only individual members.

26. Plaintiffs' claims are typical of the claims of the Class because all class members, including Plaintiffs, sustained damages in the same way as a result of Defendants' wrongdoing, and the claims of each Class member arise out of the same nucleus of operative facts and are based on the same legal theories.

27. Plaintiffs will fairly and adequately protect the interests of the Class. Plaintiffs have retained counsel who are experienced in class action and antitrust litigation, and plaintiffs have no interest in this litigation that is adverse to, or in conflict with, the interests of the other members of the class.

28. A class action is superior to the other available methods for the fair and efficient adjudication of this controversy. Plaintiffs know of no difficulty that will be encountered in the management of the claims advanced by the Class that will preclude class certification.

STATUTORY AND REGULATORY FRAMEWORK

A. Federal Regulation of New Pharmaceutical Products

29. Under the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, approval by the Food and Drug Administration is required before a new drug may be sold in interstate commerce. Premarket approval for a new drug must be sought by filing a new drug application with the FDA, under either section 355(b) or section 355(j) of the Act, demonstrating that the drug is safe and effective for its intended use.

30. New drugs that are approved for sale by the FDA are sometimes protected by a patent or patents, which provide the patent owner with the exclusive right to sell that drug in the United States for the duration of the patent or patents involved, plus any extensions. Pursuant to 21 U.S.C. § 355(b)(1), a patent holder seeking FDA approval for a new drug is required to "file with the FDA the patent number and expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug."

31. Patent information received by the FDA with respect to approved drugs is published in a book entitled *"Approved Drug Products With Therapeutic Equivalence Evaluations,"* commonly known as the "Orange Book," where it can be found and consulted by future FDA applicants.

32. Federal regulations impose strict limitations on the types of patents that an NDA holder can submit to the FDA for listing in the Orange Book. *See generally* 21 C.F.R. § 314.53. One such limitation is imposed by 21 C.F.R. § 314.53(b), which explicitly prohibits NDA

holders from listing any patent in the Orange Book unless a claim of infringement could reasonably be asserted on the basis of such a patent.

33. Despite the FDA regulations that limit the types of patents that NDA holders can list in the Orange Book, it has become common for brand companies to list any and every patent they can obtain in the Orange Book so as to force generic manufacturers to file what, as described in paragraphs 36-41 below, is commonly known as a Paragraph IV certification. The FDA does not police this practice. The FDA employs no adjudicatory or other process to determine whether a patent submitted by an NDA holder qualifies for listing under the applicable regulations. Indeed, the FDA has stated that it lacks the resources and expertise to review the patents submitted in connection with NDAs. *See* 59 Fed. Reg. 50338, 50343 (Oct. 3, 1994) ("FDA does not have the expertise to review patent information...").

34. As a result, as numerous courts have recognized, the FDA's role in the patent listing process is purely ministerial, and it relies entirely upon the good faith of the NDA holder submitting the patent for listing.

35. This unilateral ability of brand name companies to cause the listing of even the most manifestly unlistable patents in the Orange Book creates an opportunity for an unscrupulous brand name manufacturer, like Defendants, to wrongfully delay a generic competitor from bringing a lower priced generic product to market.

B. Abbreviated New Drug Applications for Generic Drugs

36. Generic drugs are drugs which the FDA has found to be bioequivalent to brand name drugs. The first generic competitor to enter a market typically does so at a price at least 30% lower than the price of the equivalent brand-name drug and quickly takes a substantial

amount of market share away from the brand-name manufacturer. As additional generic competitors come to market, the price of the generics continues to fall, and their combined market share continues to grow. In many cases, generic competitors sell products equivalent to brand-name prescription drugs for as little as 10% of the price of the brand-name drug, and have captured as much as 90% of the brand-name drug's pre-generic sales.

37. The price competition engendered by generic drug manufacturers benefits all purchasers of the drug, at all levels of the distribution chain, who are able to buy the same chemical substance at much lower prices.

38. In 1984, Congress amended the Food, Drug and Cosmetic Act by enacting the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Amendments or the Hatch-Waxman Act. Hatch-Waxman simplified the regulatory hurdles for prospective generic drug manufacturers by eliminating the need for generic companies to file lengthy and costly New Drug Applications ("NDAs") in order to obtain FDA approval. Instead, such companies are permitted to file Abbreviated New Drug Applications ("ANDAs") and to rely on the safety and effectiveness data already supplied to the FDA by the brand-name manufacturer.

39. Hatch-Waxman also added a number of patent-related provisions to the statutory scheme, as described below. Congress's principal purpose in enacting the Hatch-Waxman Amendments was "to bring generic drugs onto the market as rapidly as possible." Mova Pharmaceuticals Corp. v. Shalala, 140 F.3d 1060, 1068 (D.C. Cir. 1998).

40. Under Hatch-Waxman, a drug manufacturer may seek expedited FDA approval to market a generic version of a brand-name drug by filing an ANDA pursuant to 21 U.S.C. §

355(j). An ANDA relies on the safety and efficacy data already filed with the FDA by the manufacturer of the equivalent brand-name drug.

41. An applicant filing an ANDA for a generic version of a brand-name drug must certify to the FDA that one of the following conditions is satisfied:

> (1) the brand-name manufacturer has not filed patent information with the FDA (a "paragraph I certification");
>
> (2) the patent or patents have expired (a "paragraph II certification");
>
> (3) the patent will expire on a particular future date, and the generic manufacturer does not seek to market its generic product before that date (a "paragraph III certification"); or
>
> (4) the patent is invalid and/or will not be infringed by the generic manufacturer's product (a "paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii).

42. If an unexpired patent has been listed in the Orange Book by the brand-name manufacturer, a generic applicant is required to file either a paragraph III or a paragraph IV certification.

43. If a generic manufacturer submits a paragraph IV certification stating that a listed patent is invalid or will not be infringed, it must notify the patent owner of the filing and explain why the patent is invalid or will not be infringed. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

44. The patent owner, upon receiving a paragraph IV certification from an ANDA applicant, has 45 days in which to initiate a patent infringement action against the applicant (a cause of action created by Hatch-Waxman). If no action is initiated within 45 days, FDA approval of the generic proceeds without regard to patent issues. However, if a patent infringement lawsuit is brought within the 45-day window, the FDA is automatically barred from granting final approval to the generic applicant until 30 months after the patent holder's receipt

of the Paragraph IV certification, unless the patent expires or is held invalid or noninfringed first. 21 U.S.C. § 355(j)(5)(B)(iii). This automatic stay of FDA approval is triggered without regard to the merits of the patent holder's lawsuit.

45. The Hatch-Waxman Amendments and the federal regulations that implement them do not give the FDA authority to resolve issues of patent law. The FDA is required to accept as true information it obtains from patent holders, and to withhold its approval of new generic drugs whenever the patent holder presents a litigated dispute (whether genuine or not) regarding the validity or infringement of a patent.

46. One result of the statutory and regulatory provisions described above is that brand-name manufacturers have a strong incentive to obtain, list and enforce patents against prospective generic applicants even if the patent is ultimately held to be invalid or not infringed by the generic applicant's proposed generic drug. If a brand-name manufacturer is able to obtain a patent from the Patent and Trademark Office, list the patent in the Orange Book and bring actions under the Hatch-Waxman Act to enforce the patent, the brand-name manufacturer can effectively block the entry of generic competition for up to 30 months. This delay, which is triggered without regard to the merit of the patent holder's claim, can be worth hundreds of millions of dollars, or in this case billions of dollars, to the manufacturer of a brand-name drug.

47. Indeed, as a practical matter the brand name company *wins the lawsuit simply by filing it*, as it automatically protects its monopoly for up to two and a half years while the infringement action grinds through the court system.

SUBSTANTIVE ALLEGATIONS

A. Altana's Fraud on the Patent Office

48. Altana procured the '579 Patent from the PTO by fraud. Altana engaged in a pervasive pattern of misconduct involving deliberate misrepresentations of, and failures to disclose, highly material facts to the PTO. Absent the fraud, the '579 Patent would not have issued.

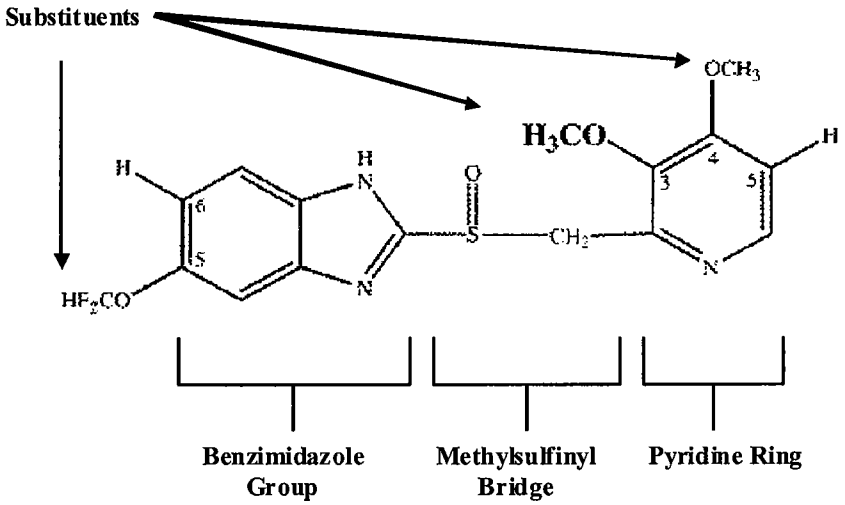
49. Applicants for United States patents have a duty of candor with respect to the PTO requiring the accurate disclosure of material information. Material information is information that a reasonable examiner would consider important in deciding whether to allow the application to issue as a patent. Applicants may not shirk their duty either by intentionally misrepresenting material facts or by intentionally withholding them from the PTO. Such conduct constitutes inequitable conduct and may render a patent unenforceable. Where, as here, the patent would not have issued absent the intentional misrepresentations and omissions, the conduct also creates antitrust liability.

50. The applicants for the '579 Patent did not invent PPIs ("proton pump inhibitors"), which were originally developed during the 1970s. In the human body, the "proton pump" is a protein located in the stomach's parietal cells that generates gastric acid for digestion. In some humans, the "proton pump" produces excess gastric acid. PPIs act to inhibit the "proton pump," thereby reducing the production of gastric acid in those patients.

51. Altana formed its own PPI development team. Altana's '579 Patent was filed during the 1980s and claims a group of structurally-related compounds—including

pantoprazole—having activity as PPIs.

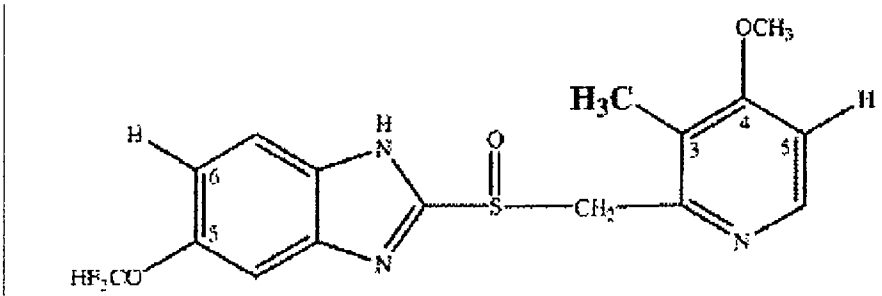
52. The compounds claimed in the '579 Patent share a common chemical backbone comprising a pyridine ring, a benzimidazole group, and a methylsulfinyl bridge connecting them ("the PPI backbone"). Pantoprazole, for example, possesses the following chemical structure:



53. Compounds having the PPI backbone, such as the compounds claimed in the '579 Patent, differ in terms of the substituents attached to the benzimidazole group and/or the pyridine ring. Pantoprazole, for example, includes a methoxy substituent (*i.e.*, OCH_3) at the 3-position and 4-position of the pyridine ring.

54. PPIs generally, and the PPI backbone in particular, were well known prior art to the '579 Patent. For example, prior art United States Patent No. 4,555,518 ("the '518 Patent") discloses a compound identical to pantoprazole, except that the substituent in the 3-position of

the pyridine ring is a methyl group (*i.e.*, CH_3) rather than a methoxy group (*i.e.*, OCH_3) as in pantoprazole.



Example 12 from the '518 Patent

55. Indeed, generally speaking, the compounds claimed in the '579 Patent have chemical structures nearly identical to corresponding prior art compounds, which are referred to herein as "prior art counterparts." The prior art counterparts are identical to the corresponding claimed compounds except for a single substitution of an alkoxy group (*e.g.*, methoxy) for an alkyl group (*e.g.*, methyl) on the pyridine ring at either the 3-position or the 5-position.

56. Altana knew its claimed compounds were *prima facie* obvious given the prior art. Indeed, the original text of the '579 Patent as filed reflects this recognition. Specifically, Altana had hoped to preempt a *prima facie* obviousness rejection through assertions in the '579 Patent application of unexpected results relative to corresponding prior art counterparts—namely, evidence of improved chemical stability at pH 5 and reduced side effects:

> It has now been found, surprisingly, that the dialkoxypyridines of the present invention have interesting and unexpected properties which advantageously distinguish them from known compounds.

'579 Patent, Column 1, Lines 40-43 (emphasis added);

> The compounds according to the invention are distinguished by the absence of substantial side effects and by a wide therapeutic range.

Id., Column 30, Lines 49-51; and

> Another advantage of the compounds according to the invention is their comparatively high chemical stability. Surprisingly, the compounds according to the invention are clearly superior (in their excellent properties) to prior art compounds.

Id.; Column 30, Lines 63-68 (emphasis added). Altana understood that evidence of unexpected results can overcome a *prima facie* obviousness rejection under appropriate circumstances.

57. Altana's statements, which were designed to preempt a PTO rejection, were false. On information and belief, Altana did not possess data supporting unexpected results at the time it filed the original Swiss patent application on June 16, 1984. Indeed, it could not have had such evidence for pantoprazole in particular because pantoprazole was not even synthesized until April 25, 1985. On information and belief, Altana likewise did not possess evidence supporting the statements at the time it filed the corresponding United States patent application on June 14, 1985.

58. In any event, however, Altana's attempt to preempt a PTO rejection was unsuccessful. Examiner Fan at the PTO appreciated the close structural relationship between the claimed compounds and their corresponding prior art counterparts. On June 10, 1986, she properly rejected all pending claims as *prima facie* obvious under 35 U.S.C. § 103(a) over either the '518 Patent or USPN 4,560,693 in view of USPN 4,255,431 ("the '431 Patent"), which teaches the interchangeability of alkoxy and alkyl groups in these types of compounds.

59. Altana did not challenge (nor could it) the very close structural relationship between the claimed compounds and the corresponding prior art counterparts. Altana did,

however, challenge the teachings of the asserted prior art references on several grounds in a response dated September 10, 1986.

60. Examiner Fan deemed Altana's arguments unconvincing and, on October 28, 1986, she renewed her prior rejections and reasoning. On January 27, 1987, Altana changed tack. It responded by arguing the allegedly "clearly unexpected properties" of the claimed compounds relating to "higher chemical stability." *See* January 27, 1987 Response to Office Action at 3. According to Altana, "[s]uch unexpectedly-improved stability is not in any way suggested by anything derived from applied art." *See id.* at 3. In support of this argument, Altana submitted the sworn declaration of its employee, Dr. Uwe Kruger ("Kruger"). It was the first of five declarations Altana would submit to obtain the '579 Patent, four of which were sworn by Kruger. According to Kruger's January 22, 1987 declaration, chemical stability in acidic environments was a known problem for PPI compounds. His declaration included stability data at pH 5 (mildly acidic conditions) for several claimed compounds and their corresponding prior art counterparts. The tests were performed in a buffer/acetonitrile solvent system and suggested a significant improvement in stability at pH 5 for the claimed compounds. Kruger stated that increased chemical stability under acidic conditions would be expected to correlate with reduced side effects.

61. On February 1, 1987, Examiner Fan rejected Altana's argument despite Dr. Kruger's sworn declaration. According to Examiner Fan, the limited number of compounds Altana tested and compared to the prior art was not sufficient to establish improved stability over the full range of claimed compounds.

62. Altana's response dated February 13, 1987 relied not merely on the existence of improved stability but rather on the degree of that improvement. It argued through its attorneys that "[w]hat is even more significant is the completely unexpected differences reflected by the provided data; this is not a question of having data which are relatively close. Most of the data provided is even of a different order of magnitude. . . ." February 13, 1987 Response to Office Action at 3 (emphasis added). Altana thus requested that Examiner Fan rely not merely on the existence of an improved stability, but also on the degree of that improvement.

63. On February 25, 1987, Examiner Fan issued a final rejection for all pending claims because, as she had explained earlier, the limited number of compounds Altana tested and compared to the prior art was not sufficient to establish improved stability over the full range of claimed compounds.

64. On April 28, 1987, Altana filed a continuation application. Contemporaneously, Altana submitted the April 24, 1987 Kruger declaration again comparing claimed compounds to their prior art counterparts. According to Kruger, the claimed compounds exhibited "significantly greater" stability than corresponding prior art counterparts. Kruger also stated that "it was not foreseeable that the compounds of FWC of SN 758,591, which have as an essential structural feature two alkoxy groups in the pyridine ring, would show a chemical stability which is unambiguously superior over known compounds, having only one alkoxy group in the pyridine ring." Kruger's statements again reflect Altana's reliance on the degree of difference in stability rather than a mere increase in stability.

65. On September 1, 1987, Examiner Fan again rejected all pending claims despite the second Kruger declaration. In her reasoning, Examiner Fan recognized the potentially limited

significance of Altana's purportedly improved stability data: "Applicants repeated stated [sic] that dialkoxy-substituted pyridine compounds are much stable [sic] chemically at PH=5 than mono-alkoxy-substituted pyridine compounds. This stability would indicate less side effect [sic]. However, applicants fail to demonstrate that the claimed dialkoxy compounds are equally or more potent in their primary use, which is to inhibit excess gastric acids or providing a protection for the stomach. It is conceivable that the claimed compounds may be less effective as in inhibiting gastric acid secretion or providing protective action for the stomach, thus greater dosage is required which would offset the advantage of less side-effect of the claimed compounds." *See* Office Action Dated September 1, 1987 at 2.

66. Examiner Fan's position made perfect sense because, if the claimed compounds had lower efficacy than their corresponding prior art counterparts, then any reduction in side effects would likely be offset by the requirement for larger doses. Examiner Fan's reasoning necessitated a comparison of the stability and efficacy differences between the claimed and prior art compounds. This also rendered highly material the degree of difference in stability and efficacy data between claimed and prior art compounds.

67. On December 17, 1987, Altana's attorney participated in an interview with Examiner Fan. The interview summary record reflects that Examiner Fan was willing to withdraw her obviousness rejection provided Altana would supplement its test data. This interview summary record makes clear that Examiner Fan's willingness to allow the '579 Patent to issue turned very specifically on Altana's testing data.

68. On February 9, 1988, Altana submitted a response to the September 1, 1987 office action and a supplement. The supplement acknowledged that "it is clear that additional evidence

had to be obtained in order to overcome outstanding grounds of rejection." *See* Response dated February 9, 1988 at 1. Altana thus recognized that the testing data was central to whether Examiner Fan would allow the '579 Patent to issue. Alongside the supplement, Altana submitted two declarations by Kruger dated December 4, 1987 and February 5, 1988 and one declaration by Dr. Konrad Heintze dated December 2, 1987. Krueger's declaration dated December 4, 1987 was responsive to Examiner Fan's comment on the relationship between stability and efficacy. It included a table comparing the relative stability and efficacy of seven claimed compounds against their corresponding prior art counterparts.

69. Kruger's stability test data was based upon a buffer/acetonitrile solvent system. Altana knew, however, no later than October 1987 that the buffer/acetonitrile solvent system unfairly exaggerated the stability comparisons in favor of its nonobviousness position.

70. More specifically, on information and belief, in an internal report dated October 15, 1987, Altana noted that due to a stabilizing effect of organic solvents such as acetonitrile, PPIs are more stable in a buffer/acetonitrile solvent system than in buffer/methanol solvent system. Thus, Altana knew no later than October 1987 that a buffer/acetonitrile solvent system would exaggerate the chemical stability of a particular PPI. This in turn would exaggerate differences between the claimed PPI compounds and their corresponding prior art counterparts. Given that Altana was relying on the degree by which stability was improved and given that the relative stability data was the focal point of the patentability analysis, information pertaining to the differences in stability between the claimed compounds and the prior art was highly material.

71. Altana's appreciation that the buffer/methanol solvent system was more appropriate than the buffer/acetonitrile solvent system is reflected by its shift to a

buffer/methanol solvent system following the October 15, 1987 report. It is also reflected by the fact that the stability data Defendants submitted to the FDA—as opposed to the PTO—was based upon a buffer/methanol solvent system rather than a buffer/acetonitrile solvent system. Despite the foregoing, Dr. Kruger's December 1987 and February 1988 PTO Declarations were based on stability data obtained in a buffer/acetonitrile solvent system.

72. On information and belief, Kruger's declarations also fail to disclose that substantially identical stability experiments had previously and/or concurrently been conducted by scientists at Altana using solutions of pHs different than 5.0. These experiments at pHs other than 5.0 indicated that the tested compounds covered by the then-pending claims of the '579 patent were not significantly more stable than their corresponding prior art counterparts.

73. Further, upon information and belief, the buffer/acetonitrile experiments reported to the PTO by the applicants for the '579 Patent were conducted at room temperature notwithstanding the fact that body temperature is a more realistic stability testing condition. Upon information and belief, scientists at Altana also conducted the acetonitrile and/or methanol solvent stability experiments at a temperature corresponding to that in the human body, in human cells, in mammals and in mammalian cells. Upon information and belief, this data did not reflect a significantly improved stability for the tested compounds covered by the then-pending claims of the '579 Patent when compared to their corresponding prior art counterparts.

74. The efficacy data in the December 4, 1987 Kruger declaration, which was based on the Heintze declaration, was similarly problematic. The Heintze declaration, in turn, included data obtained from Shay-rat testing and compared several of the claimed compounds to their corresponding prior art counterparts with respect to two efficacy parameters: (1) the reduction in

gastric acid production and (2) antiulcerogenic action (*i.e.*, reduction in ulcer size). In his declaration comparing stability and efficacy for the claimed and prior art compounds, Kruger analyzed efficacy differences between claimed and prior art compounds based only upon Heintze's antiulcerogenic action data. Kruger did not take into account the efficacy data relating to reduction in gastric acid production. Based upon the data Kruger chose to consider, he conceded that three of the claimed compounds were less potent "by a factor of about 2" as compared to their prior art counterparts but asserted that the stability was improved "by a factor of about 10 to 23." Kruger therefore concluded that the "greater dosage" required by the claimed compounds would not "offset the advantage of less side-effect." In doing so, Kruger explicitly recognized the importance of the relative magnitudes of differences in stability and efficacy data for the claimed compounds and their prior art counterparts. *See* December 4, 1987 Kruger Declaration at 2 (discussing the "stability data . . . set against the data concerning the therapeutic mode of action).

75. The patent applicants also intended to mislead the PTO when they submitted Shay-rat study efficacy data to the PTO during prosecution of the '579 Patent, by failing to also submit information known to them regarding the unreliability of the Shay-rat test method in analyzing the potency of PPIs. During prosecution of the applications to which the '579 Patent claims priority, Altana had patent applications pending in Australia ("the Australian Application"), and the European Patent Office ("the European Application") for PPIs. Both the Australian and European Applications contained efficacy data from Shay-rat studies purporting to show the claimed compounds to be superior to the prior art compound omeprazole.

76. Astra, the maker of omeprazole, challenged the Shay-rat data by submitting letters to the Australian and European Patent Offices dated December 6, 1985, and November 29, 1984, respectively. Astra challenged the Shay-rat studies as being unreliable due to a high number of "false positives." Astra cited numerous literature references, including "Gastric Antisecretory Agents," Bristol, J.A. et al., J. Med. Chem., 24 pg. 927-932, 1984, for the proposition that the Shay-rat test was a test from which "no meaningful structure-activity relationship" could be derived. The literature cited by Astra further indicated that the Shay-rat tests resulted in false positives that would skew the results in favor of greater potency of the PPIs. The literature cited by Astra further indicated that dogs provide a more specific model for testing of the claimed compounds with good correlation to activity in humans than the Shay-rat testing model. Upon information and belief, Altana abandoned the European Application after Astra's challenge, via a letter dated June 19, 1986. Upon information and belief, Altana also abandoned the Australian Application after Astra's challenge.

77. The applicants for the '579 Patent nevertheless submitted their Shay-rat study efficacy data to the PTO during prosecution of the '579 Patent without disclosing Astra's arguments or cited literature to the PTO.

78. Further, Kruger's decision to consider the antiulcerogenic data but not the reduction in gastric acid production data was not an oversight. Heintze's declaration reflected that the claimed compounds were significantly worse in terms of efficacy than their prior art counterparts when measured in terms of reduction in gastric acid production rather than antiulcerogenic action. More particularly, the claimed compounds were less efficacious by a factor of roughly 1.5 to 5 than their corresponding prior art counterparts when compared in terms

of gastric acid reduction. Indeed, an analysis between the claimed and prior art compounds based on the appropriate buffer/methanol test in conjunction with the gastric acid suppression data would reveal that the claimed compounds offered no meaningful benefit over the prior art compounds.

79. Following receipt of the aforementioned declarations and testing data in February 1988, Examiner Fan issued a Notice of Allowability. Examiner Fan relied upon the Altana declarations in deciding to allow the '579 Patent to issue.

80. Over the course of the prosecution of the '579 Patent, Altana engaged in numerous material omissions and misrepresentations, beginning with the false representations in the '579 Patent application suggesting that data existed to support the assertion of unexpected results. Altana also deliberately submitted stability testing data in a buffer/acetonitrile solvent system at a time when Altana knew that that solvent system exaggerated the stability improvement. This was particularly material inasmuch as the degree of stability improvement, rather than the mere existence of a stability improvement, was central to the patentability of the claims. Moreover, Altana opted to utilize inadequate Shay-rat testing for purposes of proving efficacy while omitting to disclose to Examiner Fan the problems known to Altana with that method. Moreover, Altana ignored unfavorable efficacy testing data relating to gastric acid suppression, choosing instead to focus Examiner Fan on the more favorable efficacy testing data pertaining to antiulcerogenic activity.

81. Examiner Fan relied on these deliberate and highly material omissions and misrepresentations.

B. Defendants Sue Generic Competitors Teva and Sun for Infringement of the '579 Patent

82. Defendants listed the '579 Patent in the Orange Book.

83. Defendants also listed U.S. Patent No. 5,997,903 in the Orange Book ("the '903 Patent.")

84. Teva Pharmaceuticals USA, Inc. (hereinafter "Teva") is the wholly-owned subsidiary of Israeli corporation Teva Industries. Teva is a manufacturer and seller of generic pharmaceutical products. On or about April 6, 2004, Teva filed an ANDA with the FDA to market a generic version of Protonix in 20mg and 40mg strengths.

85. On information and belief, on or about April 7-8, 2004, Teva gave written notice to Defendants in which Teva represented that it had filed an ANDA for pantoprazole sodium, including the accompanying certification filed with the FDA under paragraph IV stating that the '579 Patent and '903 Patents were not infringed and/or were invalid. In accordance with 21 U.S.C. § 355(j)(2)(B)(ii), the notice set forth the legal and factual bases for Teva's claims that the '579 Patent and '903 Patents were invalid and/or unenforceable and/or not infringed.

86. Within forty-five days of receipt of the notice of certification, Defendants jointly brought suit against Teva for infringement of the '579 Patent in the U.S. District Court for the District of New Jersey (Civil Action No. 04-2355). The filing resulted in an automatic 30-month stay of the FDA's authority to grant final marketing approval to Teva under its ANDA for pantoprazole sodium.

87. Defendants did not institute litigation against Teva with regard to the '903 Patent.

88. Like Teva, Sun Pharmaceutical Industries Ltd. (hereinafter "Sun") is a manufacturer and seller of generic pharmaceutical products in the United States. On or about

March 1, 2005, Sun filed an ANDA with the FDA to market a generic version of Protonix in 20mg and 40mg strengths.

89. On information and belief, on or about March 1, 2005, Sun gave written notice to Defendants in which Sun represented that it had filed an ANDA for pantoprazole sodium, including the accompanying certification filed with the FDA under paragraph IV stating that the '579 Patent and the '903 Patents were not infringed and/or were invalid. In accordance with 21 U.S.C. § 355(j)(2)(B)(ii), the notice set forth the legal and factual bases for Sun's claims that the '579 Patent and the '903 Patents were invalid and/or unenforceable.

90. Within forty-five days of receipt of the notice of certification, on or about April 13, 2005, Defendants jointly brought suit against Sun through for infringement of the '579 Patent in the U.S. District Court for the District of New Jersey (Civil Action No. 05-1966) . The filing resulted in an automatic 30-month stay of the FDA's authority to grant final marketing approval to Sun under its ANDA for pantoprazole sodium.

91. Defendants did not institute litigation against Sun with regard to the '903 Patent.

92. On April 19, 2006, while the infringement litigation against Teva was ongoing and the 30-month stay was still in effect, the FDA granted "tentative" approval to Teva for its ANDA. By granting "tentative" approval, the FDA determined that all the criteria for ANDA "final" approval had been satisfied except for the resolution of issues relating to the '579 Patent.

93. On June 22, 2006, while the infringement litigation against Sun was ongoing and the 30-month stay was still in effect, the FDA granted "tentative" approval to Sun for its ANDA. By granting "tentative" approval, the FDA determined that all the criteria for ANDA "final" approval had been satisfied except for the resolution of issues relating to the '579 Patent.

94. On June 22, 2007, Altana filed a motion for a preliminary injunction against Teva and Sun.

95. On July 31, 2007, Sun and Teva issued statements into the record in the District Court agreeing not to launch generic versions of Protonix until September 7, 2007 in order to give the Court time to render its decision on Altana's motion for a preliminary injunction against Teva and Sun.

96. Upon information and belief, the stay against Teva expired on August 2, 2007, and Teva received final FDA approval on the same day.

97. On September 6, 2007 the United States District Court of New Jersey denied Altana's motion for a preliminary injunction against Teva and Sun, holding, *inter alia*, that Altana could not demonstrate that Teva and Sun's invalidity defenses lacked substantial merit. See Altana Pharma AG v. Teva Pharms.USA, Inc., No. 04-2355, slip op. at 9-21 (D.N.J. Sept. 2007).

98. Upon information and belief, the 30-month stay against Sun expired on September 4, 2007 and Sun received final FDA approval on September 10, 2007.

99. Altana has publicly stated that it plans to launch an authorized generic version of Protonix to compete with other generic entries as a response to the early loss of exclusivity that would result from such other generics' market entry.

C. Defendants' Conduct in Procuring and Enforcing the Invalid Patent Caused Injury to Plaintiffs and the Class

100. Throughout the course of the proceedings before the PTO and the litigation of the infringement actions, Altana knowingly, willfully and fraudulently misrepresented material facts to (and concealed material facts from) the PTO in order to wrongfully obtain the '579 Patent.

But for Altana's fraud, the '579 Patent would not have issued.

101. If the '579 Patent had not issued, Defendants would not have been able to list it in the Orange Book. If the '579 Patent had not been listed in the Orange Book, Defendants would have been unable to invoke the benefits of the 30-month stays under the Hatch-Waxman Amendments.

102. Alternatively, even if the '579 Patent had issued, given the very close structural similarity between pantoprazole and the prior art, the high level of skill in the field, the strong motivation to synthesize pantoprazole and similar compounds, and the absence of objective evidence justifying the patentability of pantoprazole in view of the very close prior art, neither Altana nor Wyeth could have reasonably believed that any claims in the '579 Patent covering pantoprazole were valid or that they could prevail against generic pantoprazole ANDA filers based upon the '579 Patent.

103. As a result of the wrongful listing of the '579 Patent in the Orange Book, generic applicants were forced to include in their Protonix ANDAs, paragraph IV certifications on the basis that the '579 Patent was invalid or unenforceable, and to provide Defendants with notice of such paragraph IV certifications.

104. In response to these notices, while knowing that the '579 Patent was obtained by fraud or was otherwise invalid, Defendants commenced patent litigations against Teva and Sun in the United States District Court for the District of New Jersey. Defendants did so as part of an anticompetitive scheme to prevent any generic pharmaceutical manufacturer from successfully entering the market for Protonix in the United States for at least the 30-month period established by the Hatch-Waxman Amendments as the period during which no ANDA would be approved if

a patent infringement action against the applicant were pending.

105. As a result of Defendants's wrongful and anti-competitive conduct in fraudulently obtaining the '579 Patent; listing the '579 Patent in the Orange Book; and knowingly commencing patent litigation based on the fraudulently obtained or otherwise invalid '579 Patent, the entry of generic Protonix competition was delayed.

106. Defendants' aforesaid acts were carried out willfully, knowingly and maliciously. Defendants' acts restrained competition in interstate commerce and in the relevant market. Plaintiffs and the class have been harmed as a result of Defendants' conduct because they have been denied the benefits of competition in the market, and as a result have been cause to incur significant damages in the form of overcharges because they have been forced to pay significantly higher prices for pantoprazole.

INAPPLICABILITY OF NOERR-PENNINGTON

107. Defendants' conduct in procuring the '579 Patent and the filing of subsequent infringement suits is subject to antitrust liability for the anti-competitive effects of that suit because the asserted patent was obtained through knowing and willful fraud within the meaning of Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp., 382 U.S. 172, 177 (1965).

108. Defendants' conduct in procuring the improper listing of the '579 Patent in the Orange Book is not entitled to immunity under the Noerr-Pennington doctrine for, *inter alia*, the following reasons:

a. the FDA's conduct in listing the '579 Patent was a purely ministerial act, and thus Defendants's conduct before the FDA does not constitute legally protected petitioning

activity; and

b. the Noerr-Pennington doctrine does not immunize or protect the act of deceiving the FDA.

109. Defendants' conduct in filing and maintaining the infringement suits is not entitled to immunity under the Noerr-Pennington doctrine because such litigations were objectively and subjectively baseless within the meaning of Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc., 508 U.S. 49 (1993).

RELEVANT MARKET

110. The relevant product market is Protonix tablets and their AB-rated generic equivalents. Defendants' patented Protonix is the only delayed-release pantoprazole sodium tablet available. Sellers that desire to manufacture, market, or sell Protonix tablets and their generic equivalents in the United States must receive FDA approval. The only drug products that are freely substitutable by a pharmacist with brand-name Protonix tablets are those generic drugs that receive an AB-rating from the FDA. This rating indicates that the generic drug is therapeutically bio-equivalent to its brand name counterpart.

111. Defendants' market share in the relevant Protonix market is and has been 100% at all times in the United States.

112. Defendants' actions are part of, and in furtherance of, the illegal monopolization alleged herein, were authorized, ordered or done by Defendants' officers, agents, employees or representatives while actively engaged in the management of Defendants' affairs.

113. Defendants' illegal acts to prevent the introduction into the U.S. marketplace of any generic versions of Protonix resulted in Plaintiffs and the Class paying more than they would

have paid for Protonix and its generic equivalents, absent Defendants's illegal conduct.

EFFECTS ON COMPETITION

114. Defendants' exclusionary conduct has prevented generic entry into the relevant market, and unlawfully enabled Defendants to sell Protonix without being subject to generic competition. But for Defendants' illegal conduct, by April 19, 2006 at least one cheaper generic version of Protonix (including Defendants' own authorized generic) would have been on the market, and additional generic competitors would have entered the market thereafter.

115. If generic competitors had been able to enter the Protonix market, Plaintiffs and other direct purchaser members of the Class would have substituted lower-priced generic Protonix for the higher-priced brand-name drug for some or all of their pantoprazole requirements, and/or would have received lower prices (and/or discounts) on some or all of their remaining Protonix purchases.

116. During the relevant period, Plaintiffs and other members of the Class purchased substantial amounts of Protonix directly from Defendants. As a result of Defendants' illegal conduct alleged herein, Plaintiffs and other members of the Class were compelled to pay, and did pay, artificially inflated prices for their pantoprazole requirements, Plaintiffs and the other Class members paid prices for pantoprazole that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Class members were deprived of the opportunity to purchase lower-priced generic pantoprazole instead of expensive brand-name Protonix; and/or (2) the price of branded Protonix was artificially inflated by Defendants' illegal conduct. As a consequence, Plaintiffs and other members of the Class have sustained substantial losses and damage to their business and property in the form of

overcharges.

DAMAGES TO PLAINTIFFS AND THE MEMBERS OF THE CLASS

117. During the relevant period, Plaintiffs and the members of the Class purchased substantial amounts of Protonix directly from Defendants.

118. Plaintiffs and members of the Class have been injured in their business and property as a result of Defendants' unlawful monopolization. Plaintiffs' injury consists of paying higher prices for pantoprazole tablets than would have been paid in the absence of Defendants' unlawful conduct.

119. Defendants' exclusionary conduct delayed the sale of generic pantoprazole in the United States, and unlawfully enabled Defendants to sell Protonix at artificially inflated prices.

120. If manufacturers of generic Protonix had entered the marketplace and effectively competed with Defendants earlier, as set forth above, Plaintiffs and other members of the Class would have substituted lower-priced generic pantoprazole for some or all of their pantoprazole requirements, and/or would have received lower prices (and/or discounts) on some or all of their remaining Protonix purchases.

121. During the relevant period, Plaintiffs and other members of the Class purchased substantial amounts of Protonix directly from Defendants. As a result of Defendants' illegal conduct alleged herein, Plaintiffs and other members of the Class were compelled to pay, and did pay, artificially inflated prices for their pantoprazole requirements, Plaintiffs and the other Class members paid prices for pantoprazole that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Class members were deprived of the opportunity to purchase lower-priced generic pantoprazole instead of expensive

brand-name Protonix; and/or (2) the price of branded Protonix was artificially inflated by Defendants' illegal conduct. As a consequence, Plaintiffs and other members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges.

COUNT I

Monopolization in Violation of Section 2 of the Sherman Act

Walker Process

122. Plaintiffs incorporate by reference the preceding allegations.

123. With respect to the allegations in this count, the Protonix market is the relevant product market, and the relevant geographic market is the United States.

124. Defendants are the only suppliers in the Protonix market that are free of any threat of infringement allegations concerning the '579 Patent. Defendants listed the '579 Patent in the Orange Book for their tablet product. Defendants then asserted and relied on the '579 Patent to obtain automatic stays of final FDA approval of all ANDAs filed for the marketing of generic pantoprazole products prior to the expiration of the '579 Patent. These automatic stays were obtained by commencing litigations against generic competitors.

125. Pricing of pantoprazole remains high due to Defendants' continued enforcement of the '579 Patent, because if the '579 Patent were not in force, generic competitors such as Teva and Sun would currently be selling pantoprazole-containing products. Teva would have begun selling such products on April 19, 2006 upon the issuance by the FDA of tentative approval, which would have been a final approval but for the litigation Defendants commenced against Teva.

126. Increased competition in the Protonix market would lead to lower prices.

127. Upon information and belief, until the '579 Patent is declared invalid, unenforceable or not infringed by a court from which no appeal can be taken, a claim for damages by Altana against any of its generic competitors for infringement of the '579 Patent will be well over many millions of dollars because of $4 million plus daily U.S. sales by Defendants of their Protonix product.

128. Defendants have monopoly power in the relevant market. As a result of this monopoly power, Defendants have set and maintained artificially high prices for Protonix and reap substantial monopoly profits.

129. As described above, the '579 Patent was procured by willful and deliberate fraud and would not have issued but for that fraud.

130. Defendants appreciated this fact and nevertheless enforced the '579 Patent for purposes of maintaining their monopoly in the pantoprazole market.

131. Defendants have wrongfully, baselessly and unlawfully conspired to enforce the fraudulently procured '579 Patent to engage in predatory and anticompetitive conduct with the specific intent and for the improper purpose of monopolizing or attempting to monopolize the Protonix market, and have succeeded in achieving monopoly power and in preventing and restraining competition in that market, by enforcing the '579 Patent against competitors who have filed ANDAs for pantoprazole products in infringement litigations.

132. If the '579 Patent had not issued and/or had not been wrongfully and baselessly enforced by Defendants, at least one generic competitor would have begun marketing a generic

version of Protonix no later than April 19, 2006.

133. Defendants' exclusionary conduct delayed the sale of generic pantoprazole in the United States, and unlawfully enabled Defendants to sell Protonix at artificially inflated prices.

134. If manufacturers of generic Protonix had entered the marketplace and effectively competed with Defendants earlier, as set forth above, Plaintiffs and other members of the Class would have substituted lower-priced generic pantoprazole for some or all of their pantoprazole requirements, and/or would have received a lower price (and/or discounts) on some or all of their remaining Protonix purchases.

135. During the relevant period, Plaintiffs and other members of the Class purchased substantial amounts of Protonix directly from Defendants. As a result of Defendants' illegal conduct alleged herein, Plaintiffs and other members of the Class were compelled to pay, and did pay, artificially inflated prices for their pantoprazole requirements, Plaintiffs and the other Class members paid prices for pantoprazole that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Class members were deprived of the opportunity to purchase lower-priced generic pantoprazole instead of expensive brand-name Protonix; and/or (2) the price of branded Protonix was artificially inflated by Defendants' illegal conduct. As a consequence, Plaintiffs and other members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges.

Count II

Monopolization in Violation of Section 2 of the Sherman Act

Sham Litigation

136. Plaintiffs incorporate by reference the preceding allegations.

137. Upon information and belief, before Defendants commenced infringement litigation against its generic competitors, Defendants knew of the inequitable conduct that occurred in procuring the '579 Patent.

138. Upon information and belief, before Defendants commenced infringement litigation against its generic competitors, Defendants knew that the claims in the '579 Patent were invalid because they were obvious over the prior art.

139. Although Defendants knew that the '579 Patent was unenforceable and otherwise invalid and that the infringement litigations were baseless, Defendants nevertheless commenced and continue to prosecute such actions in an attempt to enforce the '579 Patent. Neither Altana nor Wyeth could have reasonably believed that any claims in the '579 Patent covering pantoprazole were valid and/or enforceable or that they could prevail against generic pantoprazole ANDA filers based upon the '579 Patent.

140. On information and belief, Altana and Wyeth filed suit based not upon a subjective expectation of prevailing in litigation against the generic ANDA filers, but rather based upon the subjective desire to avail themselves of regulatory delays under the Hatch-Waxman Amendments in order to improperly delay its generic competitors from entering the Protonix market, thereby further perpetuating the monopoly power of Defendants in the Protonix market.

141. Upon information and belief, Defendants have a policy of starting, maintaining and delaying legal proceedings against generic competitors in the Protonix market for the sole purpose of obtaining automatic stays of final FDA approval without regard to the merits of those actions, as evidenced by a pattern of filing, maintaining and delaying, without probable cause and/or reasonable basis, actions to enforce the unenforceable and invalid '579 Patent, thereby further perpetuating Defendants monopoly in the Protonix market.

142. Beginning April 19, 2006 and continuing to date, Defendants have been successful in precluding and delaying generic competitors from entering the Protonix market. Defendants enjoy monopoly power in the sale, distribution and pricing in the United States of pantoprazole products, preventing consumers from having a choice among competing suppliers in the Protonix market, and enabling Defendants to set and maintain artificially high prices for their Protonix product and reap substantial monopoly profits.

143. Defendants' exclusionary conduct delayed the sale of generic pantoprazole in the United States, and unlawfully enabled Defendants to sell Protonix at artificially inflated prices.

144. If manufacturers of generic Protonix had entered the marketplace and effectively competed with Defendants earlier, as set forth above, Plaintiffs and other members of the Class would have substituted lower-priced generic pantoprazole for some or all of their pantoprazole requirements, and/or would have received lower prices (and/or discounts) on some or all of their remaining Protonix purchases.

145. During the relevant period, Plaintiffs and other members of the Class purchased substantial amounts of Protonix directly from Defendants. As a result of Defendants' illegal conduct alleged herein, Plaintiffs and other members of the Class were compelled to pay, and did

pay, artificially inflated prices for their pantoprazole requirements, Plaintiffs and the other Class members paid prices for pantoprazole that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Class members were deprived of the opportunity to purchase lower-priced generic pantoprazole instead of expensive brand-name Protonix; and/or (2) the price of branded Protonix was artificially inflated by Defendants' illegal conduct. As a consequence, Plaintiffs and other members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges.

COUNT III

Monopolization in Violation of Section 2 of the Sherman Act

Wrongful Orange Book Listing

146. Plaintiffs incorporate by reference the preceding allegations

147. Defendants improperly delayed generic competition by improperly listing the '579 Patent in the Orange Book.

148. To be eligible for listing in the Orange Book, a patent must "claim [] the drug for which the applicant submitted the application or which claim [] a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale of the drug." 21 U.S.C. § 355(b)(1).

149. The FDA's role in determining which patents can be listed in the Orange Book is ministerial. The FDA is charged only with determining whether the above statutory listing requirements are met. The FDA does not, however, research whether or not a patent actually

claims the approved drug and approved method of using the drug to determine whether an applicant is misrepresenting the facts; nor does the FDA make a legal assessment as to the reasonableness or viability of an infringement claim that the brand-name manufacturer contends that it could assert against a prospective generic manufacturer. Rather, the FDA simply ensures that the brand-name manufacturer submits the appropriate documentation representing that the statutory requirements are satisfied.

150. Thus, when Defendants certified to the FDA that the statutory listing requirements were met, the FDA listed the '579 Patent in the Orange Book in reliance on Defendants' certification, without substantively evaluating its merits.

151. The '579 Patent was wrongfully listed in the Orange Book because it did not meet the criteria for Orange Book listing. The '579 Patent did not meet the criteria for Orange Book listing because Defendants could not reasonably assert a claim for infringement of the '579 Patent against a competitor that filed an ANDA to sell generic pantoprazole.

152. The goal, purpose and/or effect of Defendants' improper Orange Book listing was to delay the entry of generic Protonix.

153. But for Defendants' representations to the FDA in connection with the listing of the '579 Patent, the FDA would not have listed it in the Orange Book. If it had not been listed in the Orange Book, then generic competitors would not have been required to file Paragraph IV certifications - - and, in turn, Defendants would have been unable to invoke the 30-month stay under Hatch-Waxman.

154. If manufacturers of generic pantoprazole had been able to enter the market and compete with Defendants as early as April 19, 2006, Plaintiffs and other Class members would

have been able to substitute lower-priced pantoprazole for the higher-priced brand-name Protonix for some or all of their pantoprazole requirements, and/or would have received lower prices (and/or discounts) on some or all of their remaining pantoprazole purchases.

155. During the relevant period, Plaintiffs and other members of the Class purchased substantial amounts of Protonix directly from Defendants. As a result of Defendants' illegal conduct alleged herein, Plaintiffs and other members of the Class were compelled to pay, and did pay, artificially inflated prices for their pantoprazole requirements, Plaintiffs and the other Class members paid prices for pantoprazole that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Class members were deprived of the opportunity to purchase lower-priced generic pantoprazole instead of expensive brand-name Protonix; and/or (2) the price of branded Protonix was artificially inflated by Defendants' illegal conduct. As a consequence, Plaintiffs and other members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges.

156. Defendants' wrongful and improper Orange Book listing for the '579 Patent was an act of monopolization undertaken with the specific intent to monopolize the market for pantoprazole in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. §2.

COUNT IV

Monopolization in Violation of Section 2 of the Sherman Act

Defendants Delayed and Excluded Competition Through An Overarching Scheme

157. Plaintiffs incorporate by reference the preceding allegations.

158. Defendants used various illegal and deceptive means as a part of an overall scheme to improperly create and extend patent protection for Protonix by wrongfully manipulating the Hatch-Waxman statutory scheme, and to abuse the monopoly power created thereby. Defendants accomplished this scheme by, *inter alia*,: (1) obtaining the '579 Patent through fraudulently misleading statements, submissions, and omissions to the PTO; (2) wrongfully listing the '579 Patent in the Orange Book; and (3) wrongfully conducting baseless litigation solely to trigger the automatic 30-month stay prohibiting the FDA from granting final approval to competitors which were seeking to sell less-expensive, generic versions of Protonix.

159. The goal, purpose and/or effect of Defendants' scheme was to delay the entry of generic pantoprazole competitors which would have sold generic pantoprazole in the United States at prices significantly below Defendants' prices for Protonix, effectively causing the average market price of pantoprazole to decline dramatically.

160. The goal, purpose and/or effect of Defendants' scheme was to maintain and extend Defendants' monopoly power with respect to pantoprazole. Defendants' illegal scheme to prevent the introduction into the United States marketplace of any generic version of Protonix enabled Defendants to continue charging supra-competitive prices for pantoprazole without a substantial loss of sales.

161. As a result of Defendants' illegal scheme, Plaintiffs and the Class paid more than they would have paid for pantoprazole absent Defendants' illegal conduct. But for Defendants' illegal conduct, competitors would have begun marketing generic version of Protonix as early as April 19, 2006.

162. If manufacturers of generic pantoprazole had been able to enter the market and compete with Defendants as early as April 19, 2006, Plaintiffs and other Class members would have been able to substitute lower-priced pantoprazole for the higher-priced brand-name Protonix for some or all of their pantoprazole requirements, and/or would have received lower prices (and/or discounts) on some or all of their remaining pantoprazole purchases.

163. During the relevant period, Plaintiffs and other members of the Class purchased substantial amounts of Protonix directly from Defendants. As a result of Defendants' illegal conduct alleged herein, Plaintiffs and other members of the Class were compelled to pay, and did pay, artificially inflated prices for their pantoprazole requirements, Plaintiffs and the other Class members paid prices for pantoprazole that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Class members were deprived of the opportunity to purchase lower-priced generic pantoprazole instead of expensive brand-name Protonix; and/or (2) the price of branded Protonix was artificially inflated by Defendants' illegal conduct. As a consequence, Plaintiffs and other members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges.

164. Defendants' scheme was in the aggregate an act of monopolization undertaken with the specific intent to monopolize the market for pantoprazole in the United States, in

violation of Section 2 of the Sherman Act.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray for judgment against Defendants for:

1. A declaration that Defendants have committed the violations alleged herein;

2. A judgment for the damages sustained by Plaintiffs and the other members of the class defined herein, and for treble damages;

3. The costs of this suit, including reasonable attorneys' fees; and

4. Such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiffs demand a trial by jury on all claims and issues so triable.

Dated: December 6, 2007

Respectfully submitted,

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